

EX. 5

EXHIBIT 5

IND SUBMISSION LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
INVESTIGATIONAL NEW DRUG APPLICATION (IND)
(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) Part 312)

Form Approved: OMB No. 0910-0014
 Expiration Date: November 30, 1987.

NOTE: No drug may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40).

1. NAME OF SPONSOR Warner-Lambert Company

2. DATE OF SUBMISSION
 July 18, 1988

3. ADDRESS (Number, Street, City, State and Zip Code)
 201 Tabor Road
 Morris Plains, New Jersey 07950

4. TELEPHONE NUMBER
 (Include Area Code)
 (201) 540-4329

5. NAME(S) OF DRUG (Include all available names: Trade, Generic, Chemical, Code)
 Norethindrone Acetate and Ethinyl Estradiol Tablets, USP,
 Proprietary name: Estrostep®, Code No. CI-376

6. IND NUMBER (If previously assigned)

7. INDICATION(S) (Covered by this submission)
 Oral contraceptive

8. PHASE (S) OF CLINICAL INVESTIGATION TO BE CONDUCTED: ☐ PHASE 1 ☐ PHASE 2 ☒ PHASE 3 ☐ OTHER _____
 (Specify)

9. LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), DRUG MASTER FILES (21 CFR 314.420), AND PRODUCT LICENSE APPLICATIONS (21 CFR Part 601) REFERRED TO IN THIS APPLICATION.

IND 26,445

Loestrin® 21 1/20 NDA# 17-876

Loestrin® 21 1.5/30 NDA# 17-875

Norlestrin® 2.5 mg NDA# 13-554

Norlestrin® 21 1/50 NDA# 16-749

Norlestrin® 21 2.5/50 NDA# 16-852

Estrostep® 5/7/9 21 NDA# 19-581

10. SERIAL NUMBER:
0 0 0

IND submissions should be consecutively numbered. The initial IND should be numbered "Serial Number: 000." The next submission (i.e., amendment, report, or correspondence) should be numbered "Serial Number: 001." Subsequent submissions should be numbered consecutively in the order in which they are submitted.

11. THIS SUBMISSION CONTAINS THE FOLLOWING: (Check all that apply)

☒ INITIAL INVESTIGATIONAL NEW DRUG APPLICATION (IND)

PROTOCOL AMENDMENT(S):

- ☐ NEW PROTOCOL
☐ CHANGE IN PROTOCOL
☐ NEW INVESTIGATOR

INFORMATION AMENDMENT(S):

- ☐ CHEMISTRY/MICROBIOLOGY
☐ PHARMACOLOGY/TOXICOLOGY
☐ CLINICAL

IND SAFETY REPORT(S):

- ☐ INITIAL WRITTEN REPORT
☐ FOLLOW-UP TO A WRITTEN REPORT

☐ RESPONSE TO FDA REQUEST FOR INFORMATION

☐ ANNUAL REPORT

☐ RESPONSE TO CLINICAL HOLD

☐ GENERAL CORRESPONDENCE

☐ REQUEST FOR REINSTATEMENT OF IND THAT IS WITHDRAWN, INACTIVATED, TERMINATED OR DISCONTINUED

☐ OTHER _____
 (Specify)

Refer to the designated CFR citations before checking any of the following:

☐ TREATMENT IND 21 CFR 312.35(b) ☐ TREATMENT PROTOCOL 21 CFR 312.35(a) ☐ CHARGE REQUEST/NOTIFICATION 21 CFR 312.7(d)

FOR FDA USE ONLY

CDR/DBIND/DGD RECEIPT STAMP

DDR RECEIPT STAMP

IND NUMBER ASSIGNED:

DIVISION ASSIGNMENT:

CONTENTS OF APPLICATION

This application contains the following items: (check all that apply)

- ☒ 1. Form FDA 1571 [21 CFR 312.23 (a) (1)]
- ☒ 2. Table of contents [21 CFR 312.23 (a) (2)]
- ☒ 3. Introductory statement [21 CFR 312.23 (a) (3)]
- ☒ 4. General investigational plan [21 CFR 312.23 (a) (3)]
- ☒ 5. Investigator's brochure [21 CFR 312.23 (a) (5)]
6. Protocol(s) [21 CFR 312.23 (a) (6)]
- ☒ a. Study protocol(s) [21 CFR 312.23 (a) (6)]
- ☒ b. Investigator data [21 CFR 312.23 (a) (6)(iii)(b)] or completed Form(s) FDA 1572
- ☒ c. Facilities data [21 CFR 312.23 (a) (6)(iii)(b)] or completed Form(s) FDA 1572
- ☒ d. Institutional Review Board data [21 CFR 312.23 (a) (6)(iii)(b)] or completed Form(s) FDA 1572
- ☒ 7. Chemistry, manufacturing, and control data [21 CFR 312.23 (a) (7)]
- ☒ a. Environmental assessment or claim for exclusion [21 CFR 312.23 (a) (7)(iv)(e)]
- ☒ 8. Pharmacology and toxicology data [21 CFR 312.23 (a) (8)]
- ☒ 9. Previous human experience [21 CFR 312.23 (a) (9)]
- ☐ 10. Additional information [21 CFR 312.23 (a) (10)]

13. IS ANY PART OF THE CLINICAL STUDY TO BE CONDUCTED BY A CONTRACT RESEARCH ORGANIZATION? ☒ YES ☐ NO

IF YES, WILL ANY SPONSOR OBLIGATIONS BE TRANSFERRED TO THE CONTRACT RESEARCH ORGANIZATION? ☒ YES ☐ NO

IF YES, ATTACH A STATEMENT CONTAINING THE NAME AND ADDRESS OF THE CONTRACT RESEARCH ORGANIZATION, IDENTIFICATION OF THE CLINICAL STUDY, AND A LISTING OF THE OBLIGATIONS TRANSFERRED.

(See attached statement on the following pages)

14. NAME AND TITLE OF THE PERSON RESPONSIBLE FOR MONITORING THE CONDUCT AND PROGRESS OF THE CLINICAL INVESTIGATIONS

Jean P. Rowan, M.D. - Assistant Director, Medical Research

Kathleen Kastenholz, Pharm.D. - Senior Assistant Clinical Scientist

15. NAME(S) AND TITLE(S) OF THE PERSON(S) RESPONSIBLE FOR REVIEW AND EVALUATION OF INFORMATION RELEVANT TO THE SAFETY OF THE DRUG

Jean P. Rowan, M.D. - Assistant Director, Medical Research

Robert A. Buchanan, M.D. - Vice President, Medical Research

I agree not to begin clinical investigations until 30 days after FDA's receipt of the IND or on earlier notification by FDA. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold. I agree that an Institutional Review Board (IRB) that complies with the requirements set forth in 21 CFR Part 56 will be responsible for the initial and continuing review and approval of each of the studies in the proposed clinical investigation. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.

16. NAME OF SPONSOR OR SPONSOR'S AUTHORIZED REPRESENTATIVE

Donald R. Jaffe, Ph.D.
Assistant Director, Regulatory Affairs

17. SIGNATURE OF SPONSOR OR SPONSOR'S AUTHORIZED REPRESENTATIVE

Donald R. Jaffe

18. ADDRESS (Number, Street, City, State and Zip Code)

201 Tabor Road
Morris Plains, New Jersey 07950

19. TELEPHONE NUMBER
(Include Area Code)

(201) 540-4329

20. DATE

July 18, 1988

(WARNING: A willfully false statement is a criminal offense U.S.C. Title 18, Sec. 1001.)